



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 112

[Docket No. FDA-2011-N-0921]

RIN 0910-AG35

Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Public Meeting on Scoping of Environmental Impact Statement and Extension of Comment Period for Environmental Impact Statement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public scoping meeting; extension of comment period for the Environmental Impact Statement.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the extension of the public scoping period for Environmental Impact Statement (EIS), as well as a public scoping meeting to discuss the scope of the EIS for the proposed rule to establish standards for growing, harvesting, packing, and holding of produce for human consumption. FDA is holding a public scoping meeting as part of our ongoing efforts to seek public input on the issues and alternatives that we should consider when preparing the EIS and to provide information about the EIS process (including how to submit comments, data, and other information to the rulemaking docket), to solicit oral stakeholder and public comments on the scope of the EIS, and to respond to questions about the EIS.

DATES: See section II, “How to Participate in the Public Meeting” in the SUPPLEMENTARY INFORMATION section of this document for date and time of the public meeting, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA’s Division of Dockets Management.

Comments on the scope of issues the Agency should include in the EIS may be submitted until April 18, 2014.

ADDRESSES: See section II, “How to Participate in the Public Meeting” in the SUPPLEMENTARY INFORMATION section of this document.

You may submit comments on the scope of issues the Agency should include in the EIS, identified by Docket No. FDA-2011-N-0921 and/or Regulatory Information Number (RIN) 0910-AG35, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2011-N-0921, and RIN 0910-AG35 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information

provided. For additional information on submitting comments, see the “Request for Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, FAX or email: Rick Williams, c/o FDA EIS, 72 Loveton Circle, Sparks, MD 21152, 410-316-2377; FAX: 410-472-3289, email: [RWilliams@jmt.com](mailto:RWilliams@jmt.com).

For general questions about the meeting, to request an opportunity to make an oral presentation at the public meeting, to submit the full text, comprehensive outline, or summary of an oral presentation, or for special accommodations due to a disability: Cynthia Wise, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1357, email: [cynthia.wise@fda.hhs.gov](mailto:cynthia.wise@fda.hhs.gov).

For further information about comments for the docket: Annette McCarthy, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Public Law 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food,

Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. As part of our implementation of FSMA, we published the Proposed Rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (hereafter referred to as “the Produce Safety proposed rule”) to establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce (78 FR 3503, January 16, 2013). We recently announced plans to propose revised rule language for key parts of the Produce Safety proposed rule, including those related to water quality and the use of raw manure and compost (Ref. 1).

In publishing the Produce Safety proposed rule, we relied on a categorical exclusion from the need to prepare an Environmental Assessment or EIS under 21 CFR 25.30(j) (78 FR 3503 at 3616). However, on August 19, 2013, we issued a Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (NOI), based on additional information, including comments received, and upon further analysis. In the NOI, we explained that FDA has determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)), and therefore, an EIS is necessary for the final rule (78 FR 50358, August 19, 2013). In the NOI, FDA also announced the beginning of the scoping process and solicited public comments to identify issues to be analyzed in an EIS. The NOI asked for public comment by November 15, 2013, and FDA later extended the deadline for the public scoping period to March 15, 2014 (78 FR 69006, November 18, 2013). FDA is again extending the public scoping period to allow FDA to hold an upcoming public scoping meeting.

In this Federal Register notice, we are addressing the scope of issues for discussion at the public scoping meeting for the purpose of assisting us in determining which issues are significant

and will be analyzed indepth in the EIS (see 40 CFR 1501.7). Based on a preliminary review of comments, currently available information, and our analysis of the proposed provisions, we summarize in this document those provisions of the Produce Safety proposed rule that may significantly affect the quality of the human environment, which provisions we would include for detailed study in the EIS. In addition, as required under the National Environmental Policy Act (NEPA) and its implementing regulations, we also identify a range of potential alternatives for each issue that we plan to consider in the EIS. These are set out in table 1. We note that this EIS process is required under NEPA and is distinct from and in addition to the process FDA has announced to revise parts of the propose rule and seek comment on the revisions.

#### 1. Microbial Standard for Agricultural Water Used During Growing Activities for Covered Produce (Other Than Sprouts) Using a Direct Water Application Method

Proposed § 112.44(c) states, “When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. If you find that there is more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic Escherichia coli per 100 mL for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before you may use the water source and/or distribution system again for the uses described in this paragraph, you must either re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes

were effective; or treat the water in accordance with the requirements of § 112.43.” (Proposed § 112.3(c) defines “direct water application method” as using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water.) In addition, proposed § 112.43 includes requirements for treating agricultural water.

As noted in the NOI, public comments state that, in some regions, current irrigation practices use water that is unlikely to meet the proposed microbial standards for much, if not all, of the growing season. Consequently, if such standards are finalized, ground water is likely to be explored as a viable alternative water source for irrigation in these regions. Given recently highlighted concerns of ground water depletion in certain regions, FDA has determined that an increased use of ground water for irrigation, in response to the microbial standard in § 112.44(c), may significantly affect the quality of the human environment in those regions (78 FR 50358 at 50359).

In addition, our proposed requirements for treatment of water in § 112.43, in the context of the microbial standard, may result in changes in current practices that may significantly affect the quality of the human environment (for example, if treated tail waters are not contained or if treated effluent is not properly discharged). Therefore, we plan to consider the possible environmental impacts in the EIS resulting from these proposed provisions in addition to the environmental impacts from a range of potential alternatives to the water quality microbial standard proposed in § 112.44(c).

## 2. Minimum Application Intervals for Biological Soil Amendments of Animal Origin

Proposed § 112.56 states, in part, “If the biological soil amendment of animal origin is untreated, then the biological soil amendment of animal origin must be applied in a manner that

does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 9 months” (proposed § 112.56(a)(1)(i)); and “if the biological soil amendment of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the biological soil amendment of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 45 days” (proposed § 112.56(a)(4)(i)). Proposed § 112.54 includes provisions for acceptable treatment processes for biological soil amendments of animal origin.

Several comments received thus far have urged FDA to reevaluate the application restrictions for biological soil amendments of animal origin, which are based on the likelihood of the soil amendment harboring pathogens. As noted in the NOI, these proposed requirements, if finalized, are expected to result in changes in current use of treated and untreated biological soil amendments of animal origin or potentially greater use of synthetic fertilizers (78 FR 50358 at 50359). Changes in the type or handling of soil amendments, in response to the minimum application intervals, may significantly affect the quality of the human environment. Therefore, we plan to consider the possible environmental impacts in the EIS resulting from these proposed provisions in addition to the environmental impacts from a range of potential alternatives to the minimum application intervals proposed in § 112.56(a)(1)(i) and (a)(4)(i).

### 3. Measures Related to Animal Grazing and Animal Intrusion

Proposed § 112.82 states, in part, “At a minimum, if you allow animals to graze or use them as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered

produce, you must take the following measures: (a) An adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop.”

Proposed § 112.83(b) states, “If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing, occurs, you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112.” Further, proposed § 112.112 states: “You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta.”

We have received comments stating that these proposed requirements could potentially result in changes in current practices that would not be consistent with wildlife conservation practices and, thus, may adversely affect wildlife, including endangered and threatened species. Therefore, we plan to consider the possible environmental impacts in the EIS resulting from these proposed provisions in addition to the environmental impacts from a range of potential alternatives to the measures proposed in § 112.82(a) and § 112.83(b).

#### 4. Scope of Proposed Rule and Implications to Land Use and Land Management

Under proposed § 112.4(a), farms with \$25,000 or less of annual value of food sold are excluded from coverage of the rule. Comments to the Produce Safety proposed rule that raised environmental concerns in relation to the Produce Safety proposed rule requested that we consider increasing the \$25,000 threshold to exclude a larger number of farms from the proposed rule and, thus, reduce overall environmental impacts of the rule. Comments also suggested that the Produce Safety rule, if finalized as proposed, would cause small farmers to go out of business



and potentially result in negative environmental impacts due to changes in land use or land management. Therefore, we plan to consider the possible environmental impacts in the EIS resulting from this proposed provision in addition to the environmental impacts of potential alternatives to the \$25,000 threshold for out-of-scope farms proposed in § 112.4(a).

Table 1 provides a list of potential alternatives to each of the issues discussed previously. This table is not intended to provide a comprehensive list of issues and potential alternatives, but rather is intended to provide a range of options for environmental consideration in the EIS. We invite comment, as part of the scoping process, on whether there are other issues we should consider for indepth analysis in the EIS and any alternatives to those issues.

Table 1.--List of Issues and Corresponding Potential Alternatives To Be Considered in the Environmental Impact Statement for the Produce Safety Rule

Issue	Proposed Action	Potential Alternatives
1. Microbial standard for agricultural water	<p>A. Proposed § 112.44(c), which states:</p> <p>“When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. If you find that there is more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic <u>E. coli</u> per 100 mL for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph”</p> <p>See discussion in 78 FR 3503 at 3568-3569.</p> <p>(Proposed § 112.3(c) defines “direct water application method” as using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food-</p>	i. No action
		ii. As proposed, i.e., no more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic <u>E. coli</u> per 100 mL for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water
		iii. A detectable generic limit <u>E. coli</u> per 100 mL less stringent than proposed
		iv. A flexible water quality standard that allows for adjustment to a specified microbial quality standard based on mitigation steps that occur after application of agricultural water and prior to consumption. For example, the World Health Organization recommends a minimum microbial quality for water of 1,000 CFU generic <u>E. coli</u> per 100 mL for water used on root crops that are eaten raw, and 10,000 CFU generic <u>E. coli</u> per 100 mL for water used on leaf crops, which is dependent upon a 2-log reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1-log reduction attributed to washing prior to consumption

Issue	Proposed Action	Potential Alternatives
	contact surfaces during use of the water.)	v. For each of the options mentioned, consider the environmental impacts of two different interpretations of the definition of “direct water application method” in § 112.3(c): (1) To include root crops that are drip irrigated; and (2) to exclude root crops that are drip irrigated
2. Minimum application intervals for biological soil amendments of animal origin	A. Proposed § 112.56(a)(1)(i), which states:  “If the biological soil amendment of animal origin is untreated, then the biological soil amendment of animal origin must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 9 months”  See discussion in 78 FR 3503 at 3581, 3582.	i. No action
		ii. As proposed, i.e., applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 9 months
		iii. Applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 0 days
		iv. U.S. Department of Agriculture’s National Organic Program (USDA/NOP) application intervals for the use of raw manure as a soil amendment, i.e., 90 days or 120 days before harvest, depending on whether or not the edible portion of the crop has direct contact with the soil (as specified in 7 CFR 205.203(c)(1))
		v. Applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 6 months
		vi. Applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, and then the minimum application interval is 12 months
	B. Proposed § 112.56(a)(4)(i), which states:  “If the biological soil amendment of animal origin is treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b), then the biological soil amendment of animal origin must be applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 45 days”  See discussion in 78 FR 3503 at 3583.	i. No action
		ii. As proposed, i.e., applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 45 days
		iii. Applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 0 days
		iv. Applied in a manner that minimizes the potential for contact with covered produce during and after application, and then the minimum application interval is 90 days
3. Measures related to animal grazing and	A. Proposed § 112.82(a), which states:  “An adequate waiting period between grazing and harvesting for covered produce in any	i. No action
		ii. As proposed, i.e., an adequate waiting period between grazing and harvesting
		iii. A minimum waiting period of 9 months,

Issue	Proposed Action	Potential Alternatives
animal intrusion	growing area that was grazed to ensure the safety of the harvested crop”	consistent with proposed § 112.56(a)(1)(i) for the use of raw manure as a soil amendment
	See discussion in 78 FR 3503 at 3587.	iv. A minimum waiting period of 90 days and 120 days, consistent with the USDA/NOP-specified application intervals for the use of raw manure as a soil amendment
	B. Proposed § 112.83(b), which states:	i. No action
	“If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing, occurs, you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112”  See discussion in 78 FR 3503 at 3587.	ii. As proposed, i.e., if animal intrusion occurs, you must evaluate whether the covered produce can be harvested, and you must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated  iii. If animal intrusion is reasonably likely to occur, take measures to exclude animals from fields where covered produce is grown
4. Scope of proposed rule and implications to land use	A. Proposed § 112.4(a), which excludes farms with \$25,000 or less of annual value of food sold from coverage of the rule  See discussion in 78 FR 3503 at 3549.	i. No action
		ii. As proposed, i.e., farms with \$25,000 or less of annual value of food sold are excluded from coverage of the rule
		iii. Farms with \$50,000 or less of annual value of food sold are excluded from coverage of the rule
		iv. Farms with \$100,000 or less of annual value of food sold are excluded from coverage of the rule
		v. Farms with \$25,000 or less of annual value of covered produce sold are excluded from coverage of the rule

## II. How to Participate in the Public Meeting

FDA is holding the public meeting on the scope of the EIS for the proposed rule to establish standards for growing, harvesting, packing, and holding of produce for human consumption to inform the public of the provisions of the proposed rule that may significantly affect the quality of the human environment and anticipated alternatives we plan to consider in the EIS, to provide information about the EIS process (including how to submit comments, data, and other information to the rulemaking docket), to solicit oral stakeholder and public comments on the scope of the EIS, and to respond to questions about the EIS. The meeting will be held on April 4, 2014, from 1 p.m. until 5 p.m., at Wiley Auditorium, Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740. Due to limited space and time, FDA

encourages all persons who wish to attend the meeting to register early and in advance of the meeting. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request in advance and to provide information about the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comments and the limited time available, FDA is allocating 4 minutes to each speaker to make an oral presentation. FDA will provide opportunities to submit written comments at the meeting; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. FDA would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting. A court recorder will be available on the meeting premises to accept additional oral remarks.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the approximate time their presentation is scheduled to begin, and remind them of the presentation format (i.e., 4-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, stakeholders may submit electronic or

written comments discussing any issues of concern to the administrative record (the docket) for the rulemaking. All relevant data and documentation should be submitted with the comments to Docket No. FDA-2011-N-0921.

Table 2 of this document provides information on participation in the public meetings:

Table 2.--Information on Participation in the Meetings and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
College Park, MD Public meeting	April 4, 2014, from 1 p.m. to 5 p.m.	<a href="http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm">http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm</a>	Wiley Auditorium, Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740	
Deadline for registration	March 28, 2014	<a href="http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm">http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm</a> Docket No. FDA-2011-N-0921	We encourage you to use electronic registration if possible. <sup>1</sup>	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Request to make a Public Comment	March 28, 2014	<a href="http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm">http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm</a> <sup>2</sup>		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Request special accommodations due to a disability	March 28, 2014	Cynthia Wise, email: <a href="mailto:cynthia.wise@fda.hhs.gov">cynthia.wise@fda.hhs.gov</a>	See <b>FOR FURTHER INFORMATION CONTACT</b>	
Closing date for comments	April 18, 2014			

<sup>1</sup> For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, FAX or email, contact: Rick Williams, c/o FDA EIS, 72 Loveton Circle, Sparks, MD 21152; 410-316-2377; FAX: 410-472-3289; email: [RWilliams@jmt.com](mailto:RWilliams@jmt.com).

<sup>2</sup> You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and FAX numbers as well as the full text, comprehensive outline, or summary of your oral presentation and send to: Cynthia Wise, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 240-402-1357, email: [cynthia.wise@fda.hhs.gov](mailto:cynthia.wise@fda.hhs.gov).

### III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record for the relevant rulemaking and will be accessible to the public at <http://www.regulations.gov>. The transcript of the proceedings from the public meeting will become part of the administrative record for each relevant rulemaking. Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and at FDA's FSMA Web site at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>. It may also be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be live Webcasting and recording the public meeting. Once the recorded video is available, it will be accessible at FDA's FSMA Web site at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>.

### IV. Request for Comments

Interested persons may submit either electronic comments regarding the issues to be included in the EIS for the proposed rule to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

### V. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday and is available electronically at <http://www.regulations.gov>.

1. Statement from FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers. December 19, 2013, available from [http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm379397.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm379397.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery).

Dated: March 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.